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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	017227/0157	9876

22428 7590 09/27/2004

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,703	DOYLE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-9,11,12,37-39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3,4, 6, 7, 8, 9, 11, 12, 37, 38, 39, 41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-22-04 has been entered.

Claim Objections

Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The specification defines "early stage lung damage" as the period during which the onset and development of lung damage is undetectable or else cannot be confirmed without the aid of one or more invasive procedures (see specification at page 9, lines 11-21). As such, any patient not exhibiting a symptom specific to lung damage is deemed to be the same as the period during which the onset and development of lung damage is undetectable. Therefore, the recited limitations are not seen to further limit the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As to the claims, the claim recites, "which mammal is not exhibiting a symptom specific to lung damage". The specification does not teach which symptoms are specific to lung damage. Applicants argue that there are numerous symptoms of lung damage that are non-specific. The specification does not teach any symptoms that are specific to lung damage as recited in the claims. Therefore, the skilled artisan would be unable to determine what are specific symptoms are specifically associated with lung damage and which ones are not. Applicants rely upon *In re Johnson* 558, F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A. 1977) to provide for the negative exclusion of "which mammal is not exhibiting a symptom specific to lung disease". Applicants' arguments are not persuasive because any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the

part remaining.") see MPEP 2173.05(i). However, in the instant case there is no basis in the specification for diagnosing lung damage in a mammal exhibiting symptoms specific or non specific to lung damage. There is no description of "symptoms per se". The specification does not disclose the genus of symptoms, the particular subgenera of non-specific symptoms and those that are specific for lung damage in the specification as filed. Applicants argue that there are a multitude of non-specific symptoms. This has no written description in the specification as filed. Further it is not directed to the claim that requires not exhibiting as symptom specific to lung damage (where does the symptoms specific for lung damage have written description support in the specification as filed). There is no description of symptoms in general, symptoms non-specific to lung damage and symptoms specific to lung damage. Therefore, these alleged "symptoms" are not "positively recited" alternative elements in the specification as filed. Applicants cannot rely upon the prior art for negative exclusions.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38, 39, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38 and 39, the claims recite "which mammal is not exhibiting a symptom specific to lung damage". The specification does not teach which symptoms are specific to lung damage and therefore the metes and bounds of the patient population provided by this negative exclusion cannot be ascertained.

As to claim 8, the claim as currently drafted makes no sense. The method states monitoring for changes in the extent of lung damage which requires a priori knowledge of the presence of lung damage in a mammal, however it is unclear how this is possible in a mammal not exhibiting a symptom specific to lung damage. If the mammal has lung damage and one is monitoring for changes in the extent of.. would they not necessarily have a

symptom specific to lung damage. As such, this claim limitation in context of a mammal already known to have lung damage makes no sense.

As to claims 41 and 42, the claims recite methods of diagnosing or monitoring changes in the extent of lung damage "during a period in which the onset of lung damage cannot otherwise by confirmed without the aid of one of more invasive procedures". The specification as filed fails to define or describe the metes and bounds of this time period.

As to all the claims, the term "the body fluid" lacks antecedent basis in the independent claims. This issue is easily resolved by amending the independent claims to recite "a body fluid".

Claim Rejections - 35 USC § 102 and 103

Claims 1, 3,4, 6, 7, 8, 9, 11, 12, 37, 38, 39, 41 and 42 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00).

Doyle et al teach measuring SpA and SpB to screening for increases in a variety of patients including ventilated patients with no evidence of cardiorespiratory disease and screening for normal individuals (see page 152, Table 1) in sera (i.e. the instant blood). The "no evidence of cardiorespiratory disease" is seen to meet the limitation of "not exhibiting a symptom specific to lung damage" as instantly claimed because the ventilated patients had no evidence/symptoms of cardiorespiratory disease and is also evidence of disease and "during a period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures". Doyle et al teach that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of the lung injury (i.e. the instantly claimed lung damage). Doyle et al teach that when taken individually, daily changes in lung function were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/A. (see page 152, first full line of text). Further, the screening of

"normal individuals" also meets the limitation of the claims, since these individuals would not be exhibiting a symptom specific to lung damage. The limitation of "predisposed to developing lung damage" is also met by the normal and ventilated patients because anyone alive is predisposed to developing lung damage from any of a number of causes (chemical insult, second hand smoke, pollution/ozone, trauma, etc) since they use their lungs while alive. Further, ventilated individuals are at risk from over-expansion lung injury or injury due to bacterial infection. As such, the patient populations tested by Doyle meet the limitations of the patient population claimed herein.

In contrast to Applicants' arguments Doyle et al does meet the limitations of the claims as set forth *supra*.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Thursday 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645